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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,068	08/02/2001	Thomas E. Clemente	UNL 2977.1	5827

321 7590 08/15/2005

SENNIGER POWERS LEAVITT AND ROEDEL
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16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,068

Applicant(s)

CLEMENTE ET AL.

Examiner

Sean R. McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
4a) Of the above claim(s) 7-66 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 remain rejected under 35 U.S.C. 102(e) as being anticipated by Waterhouse et al [US 6,423,885 B1].

Waterhouse et al disclose in claims 1-14 a methods of reducing the phenotypic expression of a nucleic acid of interest by providing to the nucleus of a plant cell (eukaryotic cell) unpolyadenylated RNA (inhibits nucleus-to cytoplasm transport) comprising a target specific nucleotide sequence produced by transcription from a chimeric DNA that comprises a promoter (which can be constitutive, inducible, or tissue specific, for example; see claims 8-11) operably linked to a sense sequence corresponding to the target nucleic acid and further comprising a self splicing ribozyme preceding a DNA region involved in 3' end formation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Waterhouse et al as applied to claims 1-5 above, and further in view of Taira et al.

Waterhouse et al is relied upon as above and additionally for the teachings at columns 10, 11, and 15 where it has been taught that the chimeric DNA more than one ribozyme (self cleaving) may be contained within the chimeric DNA of the invention such that more than one unpolyadenylated RNA molecules each targeting specific nucleotide sequence is generated and it has been taught that the target specific DNA region encoding the RNA with a target specific nucleotide sequence may be different.

Although clearly embraced within the scope of the disclosure, Waterhouse et al do not specify that the different RNAs containing different target specific sequences are targeted to different genes.

Taira et al. have taught the use of constructs comprising self cleaving ribozymes to make several antisense based molecules from a vector. At column 6 it has been taught that the vectors may contain a number various concatameric units and that each concatameric unit can be targeted to different RNAs.

One in the art would clearly have combined the teachings of the prior art to make chimeric vectors as taught by Waterhouse that comprise different target specific RNAs where it has been specifically taught by Taira et al that one could clearly include inhibitory RNAs in concatameric constructs such as that taught by Taira and Waterhouse et al targeted to different RNA targets. Tiara et al have suggested that the different RNAs could be targeted at sequences of virus that are known to be different in different strains, for example.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Applicant's arguments filed 6/27/05 have been fully considered but they are not persuasive.

Applicants arguments are based on the assertion that the instant method does not require a 3'UTR. It is noted that the claims are drawn to a method where there is inhibition of nucleus-to-cytoplasm transport of *transcription products*. Claims 1 and 4-6 are devoid of any limitations drawn to a 3'UTR and applicant arguments are therefore moot in regard to those claims. Claim 2 requires that the inhibition of nucleus –to-

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cytoplasm transport [of *transcription products*] is due to lack of a *normal* 3'UTR and claim 3 requires that the inhibition of nucleus-to-cytoplasm transport [of *transcription products*] is due to a lack of a 3' terminal sequence. Applicants' pointing to the specification merely points out embodiments of their invention that are not specifically claimed. Nowhere in the claims is it required that there be no 3'UTR in the construct expressing the transcription product or in the transcription product itself. Regardless of the fact that the claims are not so limited as applicant appears to assert, the prior art clearly discloses that the construct of their methods produces a transcription product wherein the 3' end is cleaved by a self cleaving ribozyme.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

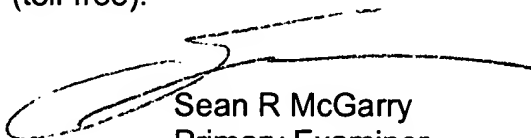
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sean R McGarry
Primary Examiner
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